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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,976	01/31/2001	Paul Sun	87165-9051	6280

23510 7590 03/15/2002

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ART UNIT	PAPER NUMBER
1638	6

DATE MAILED: 03/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/773,976	Applicant(s) SUN ET AL.
	Examiner Francis P. Moonan	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f)

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *4*
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-10 are examined in the Office Action that follows.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim is broadly drawn to any alfalfa or *Medicago sativa* plant population. The plant population, as broadly claimed, have the same characteristics and utility as those found naturally and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, and Claims 3 and 4 dependent on Claim 2 are vague and indefinite for the recitation of "ATCC Accession Number XXXXX". The recited "XXXXX" is not an ATCC Accession Number.

Claim 2 is rejected as indefinite for the applicant's recitation of the term "derived", in view of the definition of "hybrid" as defined in the instant specification on page 6, lines 6-8. The term "derive" indicates a plant produced by any subsequent generation by a multitude of unexemplified crosses to a multitude of unexemplified cultivars or species. The term "hybrid" is vaguely defined in the instant specification on page 6, lines 6-8 to "refer to a cross between a male sterile line and a pollenizer line in which at least 75% of the seeds differ genetically from the parent lines", and as such, indicates that any number of plant generations may be used to define a hybrid. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The accepted meaning is taught for example by Childers et al (1972. Agric. Sci. Rev. 10:11-18) on page 12, column 1, lines 8-22, or by Poehlman et al (1986. pp. 237-289, In: Breeding Field Crops. AVI Publishing, Westport, Conn.) for example on page 237, lines 1-7. Poehlman et al teach for example on page 237, lines 1-7 that a hybrid is "the first-generation offspring of a cross between parents with contrasting genotypes". Childers et al teach on page 13, column 1, lines 9-19 that the definition of a hybrid may be extended to an F1 population of seed produced by controlled pollination, which results in the combination of genotypes from : two or more inbred lines; an inbred line and an open pollinated variety; or a cross combining two selected clones, seed lines, varieties, or species. Childers et al teach on page 13, column 1, lines 18-20 that the "controlled pollination" requirement in the definition of a hybrid population, refers to any physical or biological method of hybridization which may produce 75 % hybrid seed.

Claim 5 and claims 6-10 dependent thereon are vague in the recitation of "controlled pollination". The phrase is vague because the recited pollination does not appear to be "controlled" by any operative.

Claim 5 and claims 6-10 dependent thereon are vague and indefinite in the recitation of "selectively harvesting seed from the cytoplasmic male sterile hybrid plants of step (a)". The phrase is vague because it is unclear as to what is intended by "selectively harvesting": whether a seed with a trait is selected for that trait and then harvested; whether a sample of seed is harvested by selective sampling from each of the individuals or a pool of seeds from the population, or whether the breeder is selecting whether to harvest at all. Furthermore, the phrase

is drawn to an indefinite multitude of selection steps and fails to set forth the metes and bounds of the invention.

Claim 5 and claims 6-10 dependent thereon are vague and confusing in the recitation of "allowing pollination". The claims are confusing because the recited "allowing pollination" include methods such as hand pollination, which would yield as high as 100% hybridity, but would lack the random pollination which would appear to give rise to a synthetic variety invention. Such hand pollination, as opposed to open pollination, is contrary to any reasonable reason for planting of plants in the 4:1 ratio as recited. If intended, applicant is advised that an amendment to line 8 of Claim 5 by inserting --open--- prior to "pollination" and after "allowing" would obviate these rejections.

Claim 7 is rejected for the use of the phrase "is accomplished employs". The phrase is awkward and the term "employs" is term not an art accepted term. Applicant is advised that substituting of "is accomplished employs" with the phrase --of the progeny of the crossing with-- would obviate this rejection, if supported by the specification.

Claim 8 is rejected for the use of the phrase "determining the hybridity is accomplished by amplified fragment length polymorphism analysis". Amplified fragment length polymorphism analysis has no "determining" capability of its own. Applicant is advised that amending the claim by substituting "by" on line 2 of the claim with --with-- would obviate this rejection.

Claim 9 is vague and confusing in the recitation of 'wherein the average seed yield of step (d) is at least 80% of the average seed yield obtainable by crossing the male fertile plant of step (c)". The claim confusing, because as broadly recited, the seed yield of step (d) includes exactly the seed yield produced by crossing by open pollination with the male fertile plant of step(c) to the second generation male sterile plants recited in step (c). Furthermore, the claim is vague as to what plants are to be compared, to make an 80% yield comparison, and fails to set forth the metes and bounds of the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is broadly drawn to any *Medicago sativa* or cultivated alfalfa seed derived with the synthetic variety Thor. Claims 2-4 are broadly drawn to any *Medicago sativa* hybrid plant or pollen or ovules from said hybrid, derived by an indefinite number of crosses from the synthetic cultivar Thor. Interpretation of ATCC Accession Number XXXXX is made in light of the pedigree disclosed in the instant specification, for example on page 2, lines 6-10, which describes to one of skill in the art a plant made with a series of alfalfa plants with arbitrary names (eg. DS9705Hyb, A833, B209, DS9761, and C580), and a population of genetically segregating alfalfa plants comprising the synthetic variety Thor. The plant names of DS9705Hyb, A833, B209, DS9761, and C580 are broadly interpreted for example in light of the instant specification on page 2, lines 6-10 and page 7, lines 9-11, and Tables 1-7 on pages 11-13 as synthetic varieties utilized by intercrossing, to make the ATCC Deposit No. XXXXX seed. Claim 5 is broadly drawn to a method of producing any alfalfa seed comprising at least 75% hybridity, comprising the steps of: (a) crossing by any controlled pollination, any first generation cytoplasmic male sterile alfalfa plant, with any male fertile maintainer alfalfa plant, to produce a second generation male sterile alfalfa seed; (b) selectively harvesting second generation male sterile alfalfa seed; (c) open pollination crossing of any second generation male sterile alfalfa plant population of any size, with any male fertile alfalfa plant, by growing said plants in a site planted in a ratio of about 4:1, arranged in any configuration in the planting block, within pollination range of any other alfalfa cultivars; and (d) non-selectively recovering the seeds from the open pollinated plants. Claims 6-8 dependent on Claim 5 are methods with the limitations that an additional step of determining the hybridity of any of the progeny produced from the crossing steps, including those determinations accomplished with genetic, morphological markers, or AFLP markers. Claim 9 dependent on Claim 5 is a method with the limitation that seed yield produced directly from the open pollination step is at least 80% of yield from the

second generation male sterile alfalfa plants. Claim 10, dependent on Claim 5 is drawn to any alfalfa seed having at least 75% hybridity. The term "hybridity" is broadly interpreted to include an analyzed proportion of an individual plant's genome as genetically hybrid, as well as the proportion of plants in a plant population which would comprise individual plants with hybrid genetic components.

The making of cytoplasmic male sterile alfalfa plants is unpredictable and genotype specific. Viands et al (1988.Chapter 30, Pollination control: mechanical and sterility. pp 931-960, In: Alfalfa and alfalfa improvement, Agronomy Monograph No. 29. Crop Sci. Soc. of America, Madison, WI) teach for example on page 939, line 21 to page 956, line 20 that alfalfa plants as a whole, being vegetatively propagated comprise a wide spectral range of female fertility and pollen infertility percentages and phenotypes, and that the combining ability of these traits in alfalfa is genotypic specific. Viands et al teach for example on page 947, line 9 to 948, line 47; page 949, line 12 to page 950, line16; page 951, line 5 to page 952, line 23, that cytoplasmic male sterility alleles are often polygenic and incompletely penetrant, and function in the context for only certain genotype combinations, since a wide range of fertility restorer genes of differing penetrance may be epistatic to any of these cytoplasmic male sterility producing alleles. Viands et al teach on page 944, line 39 to page 945, line 33, that the success of controlled pollinations may be environmentally influenced, particularly by field temperatures which affect pollen fertility, and that these responses are genotypic specific.

The making of alfalfa plants by open pollination crossing methods with cytoplasmic male sterile plants is unpredictable and genotype specific. Viands et al teach for example on page 954, lines 16-17 that competition from various mixtures of different planted alfalfa genotypes will result in genotypes eliminated from a population, and that these competitive eliminations from planted alfalfa populations are genotype-combination specific. Viands et al teach for example on page 954, lines 14-30 that maximization of forage yield , regardless of the number of genotype combinations, is genotypic-specific in alfalfa.

The utilization of genetic or molecular markers is unpredictable in a segregating germplasm within a plant species, in light of linkage disequilibrium effects. Michelmore et al (1991. PNAS(USA) 8821:9298-9832) teach on page 9829, column 1, lines 15-20 that the selective use of a small number of molecular marker analysis cannot accurately

determine overall hybridity in a species, when linkage disequilibrium and linkage drag effects predominate at a particular genomic region to which the genes encoding a trait of interest. Furthermore, Hemmat et al (1998. J. Amer. Soc. Hort Sci. 123(6):992-996) teach that DNA markers identified by genetic analysis with one population of progeny plants do not function with other populations of plants of the same species. Hemmat et al teach for example on page 992, column 1 to page 993, column 2, line 4, the use of molecular markers, with groups of 5 plant progeny from a Prima x Spartan cross, wherein each apple plant differs in expression of fast versus slow allelic forms of phosphoglucomutase (pgm), and whose pgm alleles are tightly linked to the Vf gene. Hemmat et al teach on page 993, column 2, , line 28 to page 994, column 1, line 33 that: a RAPD marker/primer DNA previously reported as being linked to the Vf gene does not produce a scorable polymorphic marker with DNAs from progeny populations derived from a Prima x Spartan cross, a Golden Delicious x Prima cross, or an Idared x NY81204-42 cross. Hemmat et al also teach for example on page 994, column 1, lines 5-6 that 4 susceptible plants from a Golden Delicious x Prima Cross lacked any of the Vf markers associated with a susceptible genotype, as determined from the DNA marker genetic mapping and bulked segregant analysis of the same DNA markers, which utilized plant progeny genomic DNA templates from a Pima x Spartan Cross. Hemmat et al also teach that in Table 2 and on page 994, column 1 lines 7-21, that of the 20 markers identified as segregating in bulked segregant analysis and genetic mapping of progeny from a Pima x Spartan cross, only 14 of these markers were scorable and useful for mapping with progeny in a Delicious x Prima cross. Furthermore, Hemmat et al teach for example on page 994, column 1, lines 23-33, that an analysis of progeny from an Idared x NY81204-42 cross indicated that only 11 of 20 DNA markers identified in bulked segregant analysis and mapping with plants with a Prima x Spartan cross produced scorable markers, and that those DNA markers that appeared to be most closely linked to the Vf gene in the progeny populations of Prima x Spartan were absent as DNA marker alleles with plants from an Idared x NY81204-42 cross.

Applicants fail to provide guidance in the instant specification which would allow one of skill in the art to know exactly how hybridity was being measured, essential to the methods and plants made as broadly claimed. Applicants fail to provide guidance as to any particular morphological marker that could be used for all alfalfa plants as broadly claimed. Applicants fail

to disclose guidance for a sufficient numbers of molecular markers such as AFLPs, which would allow a predictable assessment of hybridity, for all alfalfa plants as broadly claimed, in view of linkage disequilibrium effects. Applicant has disclosed two molecular markers for example on page, 10, lines 6-21, and their use for analysis of progeny seed collected from DS9705Hyb. Applicant fails to disclose the resulting distribution of the markers for each progeny. Applicant also fails to disclose any analysis of the molecular markers for the parental germplasm sources, which would include sampling of the synthetic populations. Provided the definition of a hybrid utilized by one of skill in the art, in the absence of information on these parental combinations, no assessment of hybridity as broadly claimed may be met, as drawn to a controlled pollination percentage of at least 75%, as described above in the 35 U.S.C. 112, second paragraph rejection, and so the marker distribution may only be a measure of the parentals' hybridity, and not the hybridity achieved by the open pollination step. Applicant fails to disclose any analysis of the parentals or synthetic parental varieties, and so the results may be merely be a skewed distribution of markers as produced from representation of hybrid parentals in the mixture, and not a 75% hybridity, as would be interpreted by one of skill in the art. In the absence of the marker distribution in the parental material that comprises the synthetic population described, the use of two markers but not their distribution in progeny or parental germplasm, one of skill in the art would consider the assessment of the hybridity of the DS9705Hyb on page 10, lines 20-21 of the instant specification as unsupported for an interpretation of 90% hybridity.

Applicants fail to provide guidance as to any particular characteristics of the alfalfa plants of the claims, with the exception of hybridity. In the absence of guidance as to exactly what from and nature of the evaluation of hybridity that is broadly claimed, one of skill in the art would not know exactly what plant with what characteristic was being claimed, as either a product or a step in a breeding process.

Applicants fail to provide guidance for methods of the production of the seed with 75% hybridity, which would take into account a wide variety of pollen fertility from alfalfa cultivars, or the incomplete penetrance of many of the cytoplasmic male sterile traits and alleles as that exist in all alfalfa plants. One of skill in the art would recognize that in consideration of these biological constraints, the open pollination planting ratio of 4:1 would not ensure a hybridity of

at least 75%, nor a yield of at least 80% in the final plants produced as claimed, in consideration of the totality of all alfalfa plants of differing pollen fertility, as broadly claimed.

Applicant fails to provide adequate guidance for essential subject matter including population sizes, specific cultivars, or genetic sources that would be applicable to making the claimed invention with all alfalfa plants. The population sizes of the individual synthetic varieties utilized to make the final synthetic are not disclosed. Applicant fails to disclose any specific cultivar parental or synthetic cultivar parental with any measure of the hybridity assigned to any of the parentals, which could allow one of skill in the art to know exactly what combination of germplasm combinations would be used and made by the claimed invention. The synthetic cultivars, synthetic (S) generation of the synthetic cultivars, or parental sources for each of the synthetic cultivars is not disclosed, and the starting syn generation and hybridity for these apparent synthetic variety parentals cannot be assessed that would be necessary to produce the composition of intercrossed parentals and synthetic cultivars that are used to make the recited synthetic variety invention.

Given the claim breadth, the unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one of skill in the art to: identify, characterize, and evaluate a multitude of alfalfa plants and plant crosses; identify, characterize, and evaluate a multitude of genetic, morphological, and molecular markers for the determination of some assessment of hybridity for a multitude of non-exemplified alfalfa plants; to develop characterize, evaluate, and develop a multitude of method steps to overcome pollen fertility, incomplete penetrance of cytoplasmic male sterility, and epistasis and linkage drag effects, to make and use the method and plant inventions as broadly claimed.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-4 are broadly drawn to a synthetic variety designated as ATCC XXXXX, alfalfa plants derived from ATCC XXXXX, and pollen and an ovule from said ATCC XXXXX-derived plants.

The representation of a synthetic variety by an adequate number of seeds is unpredictable. Fehr et al (1987. pp 417-427, In :Principles of Cultivar Development, Volume 1. Theory and Technique. MacMillan Publishing Company, New York) teach for example on page 423, Table 33-1, that as the number of parental genotypes increase in the making of a synthetic variety, the number of genotypically different individuals in the population of that synthetic variety increases, and that an estimate of the number of possible different individuals required to represent that synthetic variety population may be calculated by the formula 2^n-n+1, where n= the number of starting parents with differing genotypes. As apparent synthetic varieties, each of A83, B209,Thor, C581, and DS971 as combined to make a synthetic variety as broadly claimed, would each be expected to comprise at minimum, a series of 3 parental cultivars (at minimum, each would correspond to a 1:2:1 Mendelian distribution for a single allelic site with two alleles), and that the combination of 5 germplasm sources for ATCC No. XXXXX as disclosed for example on page 2, lines 6-10 would have a minimum of 30 genotypically different parents utilized as initial germplasm sources. Therefore, the number of different individuals required to be grown and maintained in a representative sample of the claimed synthetic variety population, would at minimum be 1,074,741,795 plant individuals (ie. greater than 1 billion plants). Furthermore, because one of skill in the art would know that a selection of seeds representing this population would be greater than this 1 billion seeds, because the probability of sequentially sampling from a larger population without selection of a duplicate genotypes would be infinitesimally small, based on sampling probability, the broadly claimed invention appears to be neither repeatable, nor capable of being represented by a deposit of seed.

Applicants fail to provide guidance as to the genetic composition, population numbers, or population structures, and how they would be combined. Applicants fail to disclose the growing of over 1 billion of individuals, which would be required for representation of the claimed synthetic cultivar, as discussed above, or any guidance as to sampling steps in the method of making which would provide guidance for one of skill in the art, that would allow them to reproduce the claimed invention. The making of the composition of the population of plants claimed as synthetic variety represented by ATCC Accession Number XXXXX, such that the population as broadly claimed could mathematically be represented by a deposit of seeds, has not been accomplished.. The specification fails to disclose a process which may be drawn to making

a reasonably representative population of seeds for the synthetic cultivar of an ATCC Deposit No. XXXXX as may be calculated by one of skill in the art. Synthetic alfalfa varietal populations of A83, B209, Thor, DS9671, C580, and B209 for example are disclosed in the instant specification on page 2, lines 6-10 and page 7, lines 9-11, and Tables 1-7 on pages 11-13 as synthetic varieties utilized by intercrossing, to make the ATCC Deposit No. XXXXX invention.

Applicants fail to provide guidance as to how effects such as reduced pollen fertility, as discussed above, would be overcome, to make and/or use the invention.

Applicants fail to provide any guidance as to any distinguishing phenotypic characteristics for the plants made by said method, which would allow one of skill in the art to know what alfalfa plants comprising what characteristics were being broadly claimed.

Given the claim breadth and lack of guidance as discussed above, undue experimentation would have been required by one of skill in the art to grow, sample, characterize, maintain, and evaluate the over one billion plants that would be required to make and use the plant method invention, and the progeny plant population products as broadly claimed.

Claim Rejections - 35 USC § 102, 102/103, and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by Northrup et al (1972 Seed Scoop 19(4):6).

Claim 1 is broadly drawn to a *Medicago sativa* or cultivated alfalfa seed included in a deposit of seed from a synthetic population designated as ATCC Accession XXXXX. It is inherent that the seed of claim one would contain seeds of Thor, or of Thor parentage, as read in light of the definition of ATCC Accession Number XXXX, read in light of the pedigree disclosed in the instant specification for example on page 2, lines 5-6, and on page 7, lines 30-

31, that A833, B209, DS9761, and Thor are designations for either synthetic populations or synthetic varieties. The arbitrary synthetic population name of DS9671, C580, and B209 are interpreted to include Thor, as interpreted by the D, C, and B designations, as discussed in the 35 U.S.C. 112, first paragraph rejections discussed above. Claim 2 dependent on claim 1 is an alfalfa plant and parts thereof, derived from a seed from the deposit of seed designated as ATCC Accession Number XXXXX, which is interpreted to include Thor plants and parts thereof. The term "derived' is interpreted to include an unexemplified number of plant crosses and plant generations

Northrup et al teach on page 6, column 3, lines 42-83 that the alfalfa cultivar Thor is a synthetic variety with a pedigree comprising Saranac, Cardinal, and Glacier plants, and that Thor, Saranac, Cardinal, and Glaciers were publicly available or for sale as early as 1972.

It is inherent that in the synthetic variety population structure, that the claimed deposited seeds would comprise a seed of one or more alfalfa genotype selected from the group consisting of Thor, Saranac, Cardinal, and Glacier.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C 103(a) as obvious over each of Northrup et al and Thompson et al (1974. Crop Science 14(4):609).

Claims 2 and claims 3 and 4 dependent theron are broadly drawn to plants and parts thereof derived from alfalfa synthetic ATCC XXXXX by an unexemplified number of plant crosses and plant generations.

Northrup et al teach on page 6, column 3, lines 42-83 the alfalfa synthetic variety Thor and the alfalfa plants of Saranac, Cardinal, and Glacier.

Thompson et al teach for example on page 609, lines 5-6, the six-clone alfalfa synthetic variety Syn-C.

Each of the Thor, Saranac, Cardinal, Glacier, plants taught by Northrup et al, or the Syn-1 plants taught by Thompson et al, differ from the claimed plants only in their derivation from a seed from a deposit with the designation ATCC XXXXX. However, a plant grown from a seed from a deposit with the designation ATCC XXXXX, as an ancestor in an unspecified number of crosses and with unspecified breeding partners would not confer a unique characteristic to the claimed plants which would distinguish them from the prior art plants, in view of the loss of the derived genetic material from a seed from a deposit with the designation ATCC XXXXX, with each cross to an unrelated partner. See *In re Thorpe*, 227 USPQ 964,966 (Fed. Cir. 1985), which teaches that a product-by process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the products.

Claim 10 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sun et al (1977. US Patent No. 4,045,912).

Claim 10 is broadly drawn to any alfalfa seed with at least 75% hybridity made by the steps of: (a) crossing by any controlled pollination, any first generation cytoplasmic male sterile alfalfa plant, with any male fertile maintainer alfalfa plant, to produce a second generation male sterile alfalfa seed; (b) selectively harvesting second generation male sterile alfalfa seed; (c) open pollination crossing of any second generation male sterile alfalfa plant population of any size, with any male fertile alfalfa plant, by growing said plants in a site planted in a ratio of about 4:1, arranged in any configuration in the planting block, within pollination range of any other alfalfa cultivars; and (d) non-selectively recovering the seeds from the open pollinated plants.

Sun et al teach in column 2, lines 17 to column 3, line 15, column 5, lines 1-33, and Replicate II of Table II that alfalfa plants produced by the open pollination planting of second generation male sterile alfalfa plants to other pollenizer cultivars planted with about 2:1, and 3:1 ratios, were determined to consist of 74.8 or 78%, and 76.3 or 85% hybridity respectively.

The Replicate II plants taught by Sun et al in Table II differ from the claimed plants only in their derivation by planting of a second generation cytoplasmic male sterile plant in a 2:1 or

3:1 ratio, as opposed to a 4:1 ratio as recited in the claims. However, the use of a different planting ratio of parentals would not confer a unique characteristic to the claimed plants which would distinguish them from the prior art plants. See *In re Thorpe*, 227 USPQ 964,966 (Fed. Cir. 1985), which teaches that a product-by process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the products.

Claim 10 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Viands et al (1988.Chapter 30, Pollination control: mechanical and sterility. pp 931-960, In: Alfalfa and alfalfa improvement, Agronomy Monograph No. 29. Crop Sci. Soc. of America, Madison, WI) in light of Pedersen et al (1973. Crop Sci 13:72-75).

Claim 10 is drawn to any population of alfalfa seed of at least 75% hybridity, produced by a particular process..

Viands et al teach on page 954, lines 1-13 the postharvest selective separation of F1 hybrid seed from nonhybrid seed by seed size, and the confirmation of the separation of hybrids by this postharvest technology by at least two independent research labs, including that of Pedersen et al.

Pederson et al teach for example on in Table 5 on page 75, that when alfalfa seed of 1.2 mg of more were selectively separated by screening with a sieve mesh size of 1.59 and 1.69 mm, that the resultants selected populations of seed consisted of 81% and 83% hybridity.

The alfalfa seed and plants taught by Viands et al and Pedersen et al differ from the claimed seed and plants only in their derivation by postharvest selective sieving of seed . However, the use of a selective sieving postharvest process would not confer a unique characteristic to the claimed plant population which would distinguish them from the postharvest prior art plant populations. See *In re Thorpe*, 227 USPQ 964,966 (Fed. Cir. 1985), which teaches that a product-by process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the products.

Claims 5, 6, and 9-10 are rejected under 35 U.S.C. 103(a) as obvious over Sun et al.

Claim 5 is broadly drawn to a method of making any alfalfa seed with 75% hybridity made by the steps of: (a) crossing by any controlled pollination, any first generation cytoplasmic male sterile alfalfa plant, with any male fertile maintainer alfalfa plant, to produce a second generation male sterile alfalfa seed; (b) selectively harvesting second generation male sterile alfalfa seed; (c) open pollination crossing of any second generation male sterile alfalfa plant population of any size, with any male fertile alfalfa plant, by growing said plants in a site planted in a ratio of about 4:1, arranged in any configuration in the planting block, within pollination range of any other alfalfa cultivars; and (d) non-selectively recovering the seeds from the open pollinated plants. Claims 6 and 9 dependent on claim 5 are respectively: a method wherein hybridity is determined in the progeny of the open pollination step; and a method wherein the average seed yield of the seed produced is 80% of the yield of seed as compared to an unexemplified cross of a male fertile alfalfa plant. Claim 10 dependent on Claim 5 is alfalfa seed with 75% hybridity.

Sun et al teach in column 2, lines 17 to column 3, line 15, column 5, lines 1-33, and Replicate II of Table II, a method of making alfalfa seed with 76.3% or 85% hybridity by the steps of: (a) crossing by any controlled pollination, any first generation cytoplasmic male sterile alfalfa plant, with any male fertile maintainer alfalfa plant, to produce a second generation male sterile alfalfa seed; (b) selectively harvesting second generation male sterile alfalfa seed; (c) open pollination crossing of any second generation male sterile alfalfa plant population of any size, with any male fertile alfalfa plant, by growing said plants in a site planted in a ratio of about 3:1, arranged in any configuration in the planting block, within pollination range of any other alfalfa pollenizer cultivars; and (d) non-selectively recovering the seeds from the open pollinated plants.

Sun et al teach in Table II the determination of the hybridity of the open pollination step. Furthermore, Sun et al teach in Replicate II of Table II that plants produced by the open pollination planting of second generation male sterile alfalfa plants to other pollenizer cultivars planted with about 1:1, 2:1, and 3:1 ratios, were respectively characterized as consisting of 54.3-57.96%, 74.8-78%, and 76.3-85% hybridity. Thus, Sun et al suggest in Table II, that an increase in male sterile to pollenizer ratios in planting results in a progressive increase in percent hybridity.

Sun et al teach in Table IV, that seed yields from three out of four populations derived by a combinations of an A x B x Saranac pedigree, with A=a cytoplasmic male sterile alfalfa, B= a maintainer line alfalfa and Saranac=an alfalfa cultivar yields 635, 890, 976, and 560 grams/plot.

Sun et al teach in Table IV, that seed yields from a synthetic population of Cayuga x Saranac produces a seed yield of 625 grams/plot. It is inherent that a comparison of the Saranac derived three-line derived plants to the two line derived plants would calculate to seed yields of 89-142% plants.

Sun et al do not teach a method using a 4:1 ratio.

It would have been an obvious design choice by one of ordinary skill in the art to utilize the method for producing a synthetic variety taught by Sun et al and modify the ratio of pollenizers from the 3:1 ratio taught by Sun et al, with the obvious correlation of ratio of planting to hybridity suggested by Sun et al, to design a method with a 4:1 ratio which could make alfalfa plants with at least an 85% increase in seed yield and 82% increase in forage yield as broadly claimed.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as obvious over Sun et al in view of Viands et al.

Claims 7 is dependent on Claim 6, and is drawn to a method comprising a step of determination of hybridity, with usage of a genetic or morphological marker .

Sun et al teach in column 2, lines 17 to column 3, line 15, column 5, lines 1-33, and Replicate II of Table II, a method of making alfalfa seed with 76.3% or 85% hybridity by the steps of: (a) crossing by any controlled pollination, any first generation cytoplasmic male sterile alfalfa plant, with any male fertile maintainer alfalfa plant, to produce a second generation male sterile alfalfa seed; (b) selectively harvesting second generation male sterile alfalfa seed; (c) open pollination crossing of any second generation male sterile alfalfa plant population of any size, with any male fertile alfalfa plant, by growing said plants in a site planted in a ratio of about 3:1, arranged in any configuration in the planting block, within pollination range of any other alfalfa pollenizer cultivars; and (d) non-selectively recovering the seeds from the open pollinated plants.

Sun et al teach in Replicate II of Table II that plants produced by the open pollination planting of second generation male sterile alfalfa plants to other pollenizer cultivars planted with

about 1:1, 2:1, and 3:1 ratios, were respectively characterized as consisting of 54.3-57.96%, 74.8-78%, and 76.3-85% hybridity.

Sun et al teach in Table IV, that seed yields from three out of four populations derived by a combinations of an A x B x Saranac pedigree, with A=a cytoplasmic male sterile alfalfa, B= a maintainer line alfalfa and Saranac=an alfalfa cultivar, yields 635, 890, 976, and 560 grams/plot of progeny seed.

Sun et al teach in Table IV, that seed yields from a synthetic population of Cayuga x Saranac produces a seed yield of 625 grams/plot. It is inherent that a comparison of the Saranac derived three-line derived plants to the two line derived plants would calculate to yields of 89-142% plants.

Sun et al suggest in Table II the determination of hybridity as part of the alfalfa breeding process.

Sun et al do not teach the use of genetic of morphological markers to determine hybridity.

Sun et al suggest in Table II, that an increase in male sterile to pollenizer ratios in planting results in a progressive increase in percent hybridity.

Viands et al suggest on page 954, lines 1-13, the determination of alfalfa hybridity by genetic or morphological markers, as part of an alfalfa breeding process.

It would have been an obvious design choice by one of ordinary skill in the art to modify the methods taught and suggested by Sun et al, and by combining them with a breeding step with a genetic or morphological marker as a measure of hybridity, as suggested by Viands et al, to make the claimed invention.

Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as obvious over Sun et al in view of Rotili et al (1995.Rasteneiev dni Nauki 32(6):15-17), and further in view of Vos et al (1995. Nucl. Acids Res. 23(210:4407-4414).

Claims 8 dependent on Claim 6 is broadly drawn to a method comprising a step of determination of hybridity with AFLP analysis (Claim 8).

Sun et al teach and suggest those aspects of alfalfa breeding as discussed in the 35 U.S.C. 103(a) rejection above.

Sun et al do not teach the use of genetic or morphological markers to determine hybridity.

Rotili et al teach for example in Table 3, the breeding of alfalfa synthetic populations.

Rotili et al suggest for example on page 71, lines 15-34 the utilization of RFLP based molecular markers for the determination of hybridity in an alfalfa breeding process.

Vos et al suggest for example on page 4407, column 2, lines 13-23, that an AFLP molecular marker may be utilized in lieu of a RFLP molecular marker in a breeding process, and that AFLPs are more robust markers than RFLP markers.

It would have been an obvious design choice by one of ordinary skill in the art to modify the methods taught and suggested by Sun et al, and by combining them with a breeding step with an AFLP molecular marker as a measure of hybridity, as suggested by Rotili et al and Vos et al, to make the claimed invention.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francis Moonan, whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday 9:00 AM to 5:00 PM (E.S.T.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4315. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Francis Moonan, Ph. D.
4 March 2002

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